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EXAMINER

LAMPRECHT, JOEL

ART UNIT

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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,184	Applicant(s) SHER, ARIEH	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 16-31 are objected to because of the following informalities: In Claim 16, the newly amended limitations to step a) do not set forth any additional structural limitations. Examiner has taken note of page 15 line 28, and acknowledges that Applicant is able to act as their own lexicographer; however, it is unclear from the specification what structural differences are explicitly defined by "non-crossing the lesion imaging guidewire". Regarding claim 20 line 2, "operates" should be "operate". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 16-25, 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al (5,993,469) in view of Pomeranz (US 5,938,609) and in further view of Selmon et al (US 2001/0018596 A1). McKenzie et al disclose a method and apparatus for reducing restriction of blood flow in a lumen of a blood vessel comprising inserting imaging system into the lumen capable of generating cross-

sectional images of the lumen (Col 9 Line 35-50, Col 11 Line 65-Col 12 Line 65, Col 18 Line 30-45), propelling a catheter including a “working head” with imaging system to the plaque (Col 11 Line 16-65), scanning the lumen with the imaging system to image the lumen (Col 11 Line 65-Col 12 Line 65), positioning the catheter in the lumen using a position element and monitoring the image to determine if the head is positioned in a desired location (Col 18 Line 5-45), and finally operating the working head to remove the intraluminal plaque (Col 19 Line 10-Col 20 Line 5). The working head disclosed by McKenzie et al contains a cutting edge which is operative when rotated and is capable of operation prior to traverse of the plaque (Col 16 Line 35-60), positioning elements include a number of balloons which can circumferentially surround the catheter (Col 18 Line 5-45), contains a control system which can aid in positioning, scanning, inserting, monitoring (Col 12 Line 35-Col 13 Line 17, Col 19 Line 10-30), and operating the device and can be operated by inputs from the operator, a removal device including for removal of the plaque (Col 17 Line 50-Col 18 Line 3), a therapeutic lumen and a central vacuum lumen for removal of the plaque removed by the cutting device (Col 12 Line 10-35)

McKenzie et al do not disclose the use of an “imaging guidewire” rather the use an imaging system attached to the working head of the system. Attention is then directed to the secondary reference by Pomeranz in the same area of endeavor which discloses the use of an imaging guidewire to function both as a standard guidewire, as well as an imager to monitor the therapeutic procedure (Col 3 Line 20-42). The imaging guidewire of Pomeranz allows for the introduction of a therapeutic catheter over the

imaging guidewire for the purpose of reducing the amount of time the procedure takes as well as reducing the amount of stress on the blood vessel wall (Col 7 Line 20-62, Column 2 Line 15-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the imaging guidewire system of Pomeranz with the plaque-removal system of McKenzie et al to reduce operation time and to prevent blood vessel damage (Col 2 Line 15-22).

McKenzie et al and Pomeranz do not disclose a method comprising advancing a guidewire only up to the intraluminal plaque, rather they advance past the occlusion. Attention is then further directed to the teaching reference by Selmon et al which teaches a method for guidewire advancement to only the distal portion of an occlusion to allow for a working head to traverse the plaque in cases where the concretion or plaque is not able to be crossed by the guidewire alone (0015). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the teachings of Selmon et al with the imaging guidewire and plaque removal methods of McKenzie et al and Pomeranz for the purpose of providing a method for treating a “fully occluded” or solid occlusion of the blood vessel without bypass (0003, 000—0006).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al in view of Pomeranz and in further view of Selmon et al as applied to claim 16 above, and further in view of Findlay et al (US 6,623,495 B2). McKenzie et al in view of Pomeranz and in further view of Selmon et al disclose all that is listed above, but fail to mention the use of an “Archimedes Screw” incorporated into the design to

facilitate removal of a portion of the plaque. Attention is then directed to the teaching reference by Findlay et al which discloses the use of an Archimedes screw in the same area of endeavor in conjunction with a guidewire for the purpose of plaque removal (Col 5 Line 51-Col 6 Line 25). It would have been obvious to one of ordinary skill in the art to have used the Archimedes screw functionality of Findlay et al with the imaging guidewire plaque removal system of McKenzie et al in view of Pomeranz and Selmon et al for the distinct purpose of improving plaque removal after and during a cutting procedure within the vessel.

Claims 14, 15, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al in view of Pomeranz and in further view of Selmon et al as applied to claims 1 and 16 above, and further in view of Masch (US 4,728,319). McKenzie et al in view of Pomeranz and in further view of Selmon et al discloses all that is listed above but fail to include specifics on the rotational speeds of the cutting head. As the listed RPMs within the current applications are outside of the norms for traditional cutting with a high speed head attention will be directed to the secondary reference by Masch that describes the use of a cutting element with a screw-like design which is used at 10-60 RPM for the removal of plaque elements within the body (Fig 1-5, Col 6 Line 20-55). It would have been obvious to one of normal skill in the art at the time of the invention to have enhanced the teachings of McKenzie et al in view of Pomeranz and Selmon et al with those of Masch et al to provide a low-speed cutting element for removal of plaque within arteries of the body.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The Claim Objections from the previous action have been withdrawn in light of the amendments made to the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/Ruth S. Smith/
Primary Examiner, Art Unit 3737